

Application Serial No.: 09/925,941

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### REMARKS

Prior to this amendment, claims 1-4 and 6-12 were pending. Claim 1 is amended for clarity. Support for this amendment is found at p. 26, lines 9-34. Claims 2-4 and 7-12 are amended for proper antecedent basis. Claims 13 and 14 are new. Support for claim 13 is found at p. 26, lines 25-34. Support for claim 14 is found at p. 27, lines 1-7. No new matter is introduced by way of this amendment.

#### Interview

Applicant appreciates the Examiner's participation in a teleconference with Applicant's representative on September 3, 2004. In the interview Applicant's representative and the Examiner discussed potential amendments for overcoming the rejection of the claims. In particular they discussed the use of array images and alignment of these images. While Applicant's representative and the Examiner did not agree to any claim amendments, Applicant submits that the claims as amended herein, overcome the rejection of the claims, as set forth below, for at least the reasons discussed in the interview.

#### Rejection Under 35 U.S.C. § 112, first paragraph

Claims 6-10 and 12 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner stated that the recitation "when no bleed-through occurs" is added, however, the specification allegedly fails to define or provide any disclosure to support such claim recitation. Applicant respectfully traverses.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, SF-1149152 1

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e.g., Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); MPEP 2163. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Univ. of California v. Eli Lilly 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991); MPEP 2163. However, the invention need not be described in *ipsis verbis* in order to satisfy the description requirement. In re Luckach, Olson and Spurlin, 169 U.S.P.Q. 795, 796 (CCPA 1971). It is only required, for example, that the specification describe the invention sufficiently for those of ordinary skill in the art to recognize that the applicant invented the subject matter he now claims. In re Voss, 557 F.2d 812, 194 USPQ 267, 271 (CCPA 1977).

Here, Applicant submits that the specification, including the description and the drawings provide adequate written description of measuring a signal when no bleed-through occurs, in accordance with the claims, such that one of ordinary skill in the art would know that Applicant invented the subject matter they now claim.

Applicant respectfully notes that in addition to the portion of the specification referred to by the Examiner in the office action (citing page 31, line 30 through page 33, line 30), in the prior response to office action Applicant also pointed to Figure 3. In

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addition, Applicant draws the Examiner's attention to the figure 3 description on p. 6, lines 1-3 of additional language supporting this claim recitation. Here, the specification recites that

Figure 3 exemplifies the signal obtained when detecting a signal with multiple different channels (C1, C2, C3 and C4).  
A. Signal detected when *no bleed-through is detected*. B  
Signal detected when bleed-through signal is detected.  
(emphasis added)

Accordingly, Applicants submits that upon reading the instant specification, including figure 3, the description of figure 3 and page 31, line 30 through page 33, line 30, one of ordinary skill in the art clearly would appreciate that the inventors of the present claims were in possession of the claimed subject matter including measuring a signal "when no bleed-through occurs". Applicant respectfully requests the Examiner to withdraw the rejection.

Rejection Under 35 U.S.C. § 112, second paragraph

Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in the recitation "the respective subpopulation of microspheres" because the recitation lacks proper antecedent basis in the claim. In response, Applicant has amended the claim thereby obviating the rejection. Applicant respectfully requests the Examiner to withdraw the rejection.

Rejection Under 35 U.S.C. § 102/103

Claim 12 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lockhart et al (U.S. Patent No. 6,040,138).

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Claim 12 is directed to a method of signal pre-processing comprising deriving first and second reference signals from first and second subpopulations of discrete sites on a substrate, the deriving comprising detecting a first signal from each of said first and second subpopulations in first and second channels determining the theoretical signal for the first signal, wherein the theoretical signal comprises the expected signal obtained from the first signal when measured in the first and second channels, when no bleed-through occurs, determining a threshold similarity measure for the first signal, the determining comprising comparing the reference with the theoretical signal, and comparing a second signal from the first and second subpopulations with the threshold similarity measure, wherein the second signal is obtained by a method comprising detecting the second signal from the first and second channels, wherein when the second signal is within the threshold similarity measure, the first discrete site contains a positive signal.

Lockhart is directed to a method of monitoring expression levels of genes. The method includes comparing experimentally determined fluorescence intensities from nucleic acid arrays with intensities obtained from reference samples.

The Examiner's position appears to be that Lockhart teaches each element of claim 12, but is silent with respect to teaching bleed-through. According to the Examiner, "the absence of bleed-through is deemed to be inherent in the fixed excitation illumination and comparison of absolute intensities in Lockhart et al (Column 23, lines 42-56), because Lockhart desires exact illumination and detection and hence absence of bleed through. Applicant respectfully traverses.

As the Examiner is aware, "[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). In addition,

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Applicant notes that inherency must be a necessary result and not merely a possible result. In re Oelrich, 212 USPQ 323 (CCPA 1981).

Applicant submits that Lockhart fails to teach each element of claim 12. First, as noted by the Examiner, Lockhart is silent with regard to bleed-through.

The Examiner suggests that the absence of bleed-through disclosure in Lockhart is deemed to be inherent in the fixed excitation illumination and comparison of absolute intensities in Lockhart et al. The Examiner relies on column 23, lines 42-56 as providing the allegedly anticipating disclosure. Applicant traverses.

As noted previously, inherency must be a necessary result and not merely a possible result. Here, Applicant submits that not only is the result not a necessary result, it is not a possible result based on the disclosure in Lockhart. As noted previously, there is no teaching in Lockhart, and the Examiner has pointed to none, of any disclosure that teaches detecting a signal in more than one channel. Absent a teaching of detection in more than one channel, it is not possible to evaluate bleed-through. As the Examiner noted at p. 3, paragraph 4 of the Office Action of July 12, 2004, bleed-through refers to a signal that includes over-lapping bandwidth frequencies. Without analyzing such a signal in multiple, e.g. more than one, detection channel, one would not be aware of such bleed-through signal. Accordingly, Applicant submits that measuring signal in the absence of bleed-through is not an inherent teaching or result found in Lockhart.

Furthermore, Applicant disagrees with the assertion that Lockhart desired exact illumination and detection and hence absence of bleed through. Even if Lockhart did indeed have such a desire, the mere desire does not necessarily remove the bleed-through absent some indication that the desire was acted upon and was successful in substantially removing bleed-through. Otherwise it is quite possible that bleed-through

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was present during the measurements of Lockhart. Thus, the requirement that the relied upon inherency be a necessary result is not established nor is anticipation.

Second, Applicant notes that the Examiner has failed to point to any teaching or suggestion in Lockhart describing detecting a first signal in first and second channels. Specifically, the section the Examiner pointed to (col. 23, lines 47-56) describes measuring probe signal strength at each location of an array and further describes choosing signal thresholds. However, this section is at best directed to single channel detection and does not teach or suggest detecting a signal in more than one channel.

Third, the Examiner has pointed to no disclosure in Lockhart of determining the theoretical signal for a first signal, wherein the theoretical signal comprises the expected signal obtained from the first signal when measured in the first and second channel, as recited in part (b) of claim 12, much less doing so when no bleed through occurs, as also recited in part (b) of claim 12. Applicant respectfully submits that Lockhart does not teach or suggest the method of claim 12 including, for example, part (b) and requests that the rejection be removed at least on this basis. However, should the Examiner maintain the rejection, Applicant respectfully requests that the Examiner point to any description of part (b) of claim 12 in the cited references that is relied upon.

Finally, Applicant submits that the Examiner has failed to point to any teaching or suggestion in Lockhart of comparing a second signal with the threshold similarity measure, wherein the second signal is obtained by a method that includes detecting the second signal from first and second channels, as recited in part (d) of claim 12. Applicant respectfully submits that Lockhart does not teach or suggest the method of claim 12 including, for example, part (d) and requests that the rejection be removed at least on this basis. However, should the Examiner maintain the rejection, Applicant respectfully requests that the Examiner point to any description of part (d) of claim 12 in the cited references that is relied upon.

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Accordingly, Applicant submits that Lockhart fails to anticipate claim 12. Applicant respectfully requests the Examiner to withdraw this rejection.

The Examiner suggests an alternative theory upon which to base a rejection of claim 12. The Examiner suggests that claim 12 is obvious over Lockhart.

The Examiner's position seems to be that although Lockhart is silent with regard to bleed-through, it would have been obvious for one of ordinary skill in the art to modify the method of Lockhart and to measure signals when no bleed through occurs for the expected benefit of exact illumination and detection as they desire. Applicant respectfully traverses.

As the Examiner is aware, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, the prior art must provide one of ordinary skill in the art with a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or to combine their teachings. See WMS Gaming Inc. v. Int'l Game Tech., 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). A valid rejection under 35 U.S.C. § 103 based upon a single prior art reference must be supported by some suggestion of the claimed invention or motivation to reach the claimed invention which is found in that single prior art reference. In reLaskowski, 10 USPQ2d 1397 (CAFC 1989). Second, the prior art must provide one of ordinary skill in the art with a reasonable expectation of success. The skilled artisan, in light of the teachings of the prior art, must have a reasonable expectation that the modification or combination suggested by the Examiner would be successful. See In re Dow, 5 USPQ2d 1529 (Fed. Cir. 1988). Third, the prior art, either alone or in combination, must teach or suggest each and every limitation of the rejected claims. The teaching or suggestion to the make the claimed invention, as well as the reasonable expectation of success, must come from the prior art, and not in Applicants'

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disclosure. See In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991). If any one of these criteria is not met, *prima facie* obviousness is not established.

Here, the Examiner has acknowledged that Lockhart is silent with respect to bleed-through. Moreover, Applicant submits that Lockhart is deficient in teaching several of the limitations of claim 12, as noted above. Accordingly, Applicant submits that the cited reference fails to teach or suggest each and every element of claim 12. As such, a *prima facie* case of obviousness has not been established. Applicant respectfully requests that the rejection be removed at least on this basis.

Even if the examiner maintains that all elements of the claims are suggested in the cited art, Applicant submits that the Examiner has failed to point to any teaching or suggestion that would have motivated one of ordinary skill in the art to modify the teaching of Lockhart to reach claim 12. The Examiner suggests that it would have been obvious to one of ordinary skill in the art to modify the method of Lockhart and to measure signals when no bleed through occurs for the expected benefit of exact illumination and detection, as they desire.

However, initially, Applicant notes that the Examiner has not pointed to any teaching in the art of record to support the alleged motivation. Moreover, Applicant does not find any disclosure in Lockhart regarding "exact illumination and detection as they desire". Should the Examiner maintain this rejection, Applicant respectfully requests evidence in support of the Examiner's position that Lockhart or any of the cited art discloses or suggests, "exact illumination and detection as they desire." See M.P.E.P. § 2144.03.

For at least the above reasons, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness. Applicant respectfully requests the Examiner to withdraw the rejection.

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Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (6,327,410) in view of Gingeras (6,228,575)

Amended claim 1 (from which claims 2-4 depend) is directed to a method of determining the presence of a target analyte in a sample comprising acquiring a first image of a random array composition comprising a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent, wherein the microspheres are distributed on the surface such that each of the discrete sites contain no more than 1 microsphere. The method further includes storing the first image in a computer readable memory to generate a first stored image, mapping a grid onto said first stored image to create a registered first image, wherein the mapping includes positioning the image on the grid and repositioning the grid or the image in one or more directions to align the grid with the image. The method further includes contacting the random array composition with the sample, acquiring a second image from the array with the sample, storing the second image in a computer readable memory to generate a second stored image, mapping a grid onto said second stored image to create a registered second image, wherein the mapping comprises positioning the image on the grid and repositioning the grid or image in one or more directions to align the grid with the image, and comparing the first and said second registered images in the computer readable memory to determine the presence or absence of said target analyte.

Walt is directed to a microsphere-based analytical chemistry system and method for making the same in which microspheres or particles carrying bioactive agents may be combined randomly or in ordered fashion and dispersed on a substrate to form an array while maintaining the ability to identify the location of bioactive agents and particles within the array using an optically interrogatable, optical signature encoding scheme.

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Gingeras is directed to methods and arrays for speciating and phenotyping organisms. The methods include inputting into a computer nucleic acid sequences and additionally, inputting hybridization intensities for the known nucleic acid sequences. A database of the species and hybridization patterns of the known nucleic acid sequences also may be generated.

The Examiner's position appears to be that Walt discloses each element of the claims except they do not specifically teach their obtained images are stored in a computer readable memory. However, according to the Examiner, data image storage, comparison and analysis for target analyte determination was well known in the art at the time the invention was made as taught by Gingeras. Applicant respectfully traverses.

The legal requirements to establish a *prima facie* case of obviousness are set forth above.

Here, Applicant submits that the combination of references fails to teach each element of the claims. As noted previously, present claim 1 recites, *inter alia*, that the method includes mapping a grid onto a first stored image, wherein said mapping includes positioning the image on the grid and repositioning the grid or the image to align the grid with the image. However, Applicant submits that neither reference individually or when combined teach such a method.

The Examiner points to Walt at col. 19, lines 31-52, for the teaching of mapping a grid because Walt discloses the use of matrices to identify the locations of beads when the arrays are filled one bead population at a time. However, such a method when viewed alone or in combination with the description in Gingeras et al. does not teach or suggest the presently claimed method in that the presently claimed method includes the

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additional steps of positioning an image on a grid and repositioning the grid or the image to align the grid with the image.

In addition, Applicant submits, even assuming, *arguendo*, that all claim elements were taught in the combination of the references, there is inadequate motivation for the combination of the references. Applicant notes that the prior art must be considered in its entirety, including disclosures that teach away from the claims (see MPEP § 2141.02) and that a proposed modification cannot render the prior art unsatisfactory for its intended purpose or change the principle of operation of a reference (see MPEP § 2143.01). Applicant respectfully reminds the Examiner that a reference teaches away if it leaves the impression that the product would not have the property sought by the applicant. See In re Caldwell, 50 C.C.P.A. 1464, 319 F.2d 254, 138 USPQ (BNA) 243, (CCPA 1963).

To this end, Applicant notes that Gingeras is directed to methods that utilize ordered arrays for detecting species specific genes in order to identify a particular species of organism in a target sample. The method involves inputting hybridization data regarding different probe sequences and comparing different hybridization data to identify the species in the sample. However, Applicant submits that this disclosure is inapplicable to the present claims because the present claims are directed to *image* comparison. Applicant submits that one of ordinary skill in the art would not be motivated to combine the references to arrive at the present claims because this aspect of the Gingeras disclosure is simply not relevant to the claims and therefore, a combination of the references would leave the impression that the method resulting from the combination of the references would not have the property sought by the applicant.

Alternatively, Gingeras briefly mentions that images of arrays can be compared. Column 25, lines 20-39 set forth that "[i]t is also possible to perform the experiment by

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hybridizing the reference and unknown to two different chips in parallel under identical conditions...sequences can be identified by directly comparing hybridization amplitude signatures." Thus, at best, Gingeras mentions comparing different arrays that were hybridized under identical conditions. However, Applicant submits that this disclosure actually teaches away from a combination with Walt. As noted previously, Walt utilizes random bead arrays. Because the arrays are prepared such that beads are distributed on a substrate in a random fashion, no two arrays are the same, even if they are made with the same bead pool. As such, side by side comparison of images from such arrays, according to the methods of Gingeras, would not provide useful information because the identity of the bioactive agents at each location on the two arrays is different. Accordingly, the alleged combination would be cumbersome at best and practically inoperable such that one of ordinary skill in the art would not be motivated to combine this teaching of Gingeras with the random array of Walt.

Accordingly, Applicant submits that based upon a consideration of the references in their entirety as required (see MPEP § 2141.02), one of ordinary skill in the art would not have been motivated to combine teachings of the cited references to reach the claimed invention.

As such, Applicant submits that the references alone or in combination fail to teach each element of the claims. Moreover, Applicant submits that there is inadequate motivation for the combination of the references. Applicant submits that that a *prima facie* case of obviousness has not been established. Applicant respectfully requests the Examiner to withdraw the rejection.

Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (6,327,410) in view of Lockhart (6,040,138).

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Claim 6 is directed to a method of signal pre-processing comprising acquiring a first data image of a random array composition comprising a substrate with a surface comprising discrete sites and a population of microspheres comprising at least a first and a second subpopulation each comprising a bioactive agent wherein the microspheres are distributed on the surface such that the discrete sites contain microspheres and determining the similarity of a first signal from at least one discrete site to at least one reference signal, wherein the determining comprises obtaining the first signal from the at least one discrete site and comparing the first signal to a threshold similarity measure obtained by comparing a reference signal to a theoretical signal, wherein when the first signal is within the threshold similarity measure, the first discrete site contains a bead, wherein the first signal is derived from signals obtained by measuring a first signal in first and second channels, the reference signal is derived from signals obtained by measuring the reference signal in the first and second channels and the theoretical signal is the signal expected to be obtained from a first signal when measured in first and second channels when no bleed-through occurs.

Walt is described above.

Lockhart also is described above.

The Examiner's position appears to be that it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the threshold measure of Lockhart et al to the signal detection and comparison of Walt to determine the presence of absence of a bead, to discard a signal below the threshold and to accurately analyze and distinguish signals from background signals as taught by Lockhart. Applicant respectfully traverses.

Here, Applicant submits that the combination of references fails to teach the method as claimed. Specifically, as noted above in regard to the rejection for claim 12,

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Lockhart is silent with respect to bleed-through. Furthermore, Lockhart does not teach or suggest a method that includes detecting a signal wherein the first signal is derived from signals obtained by measuring a first signal in first and second channels. In addition, Lockhart does not teach or suggest a method that includes the use of a reference signal as claimed, wherein the reference signal is derived from signals obtained by measuring the reference signal in first and second channels.

In addition, Applicant notes that the Examiner has failed to point to any teaching in Walt that would cure the deficiencies of Lockhart. As such, Applicant submits that the references, either alone, or in combination, do not teach each element of claims 6-10.

As such, Applicant submits that a *prima facie* case of obviousness has not been established. Applicant respectfully requests the Examiner to withdraw the rejection.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart (6,040,138) in view of Walt et al. (6,327,410).

Claim 11 is directed to a method of signal pre-processing comprising acquiring a reference signal from a first and a second subpopulation of discrete sites on an array, wherein the reference signal is derived from detecting a first signal in first and second channels, determining a threshold similarity measure of the reference signal from the first and second discrete sites by determining the difference between the reference signal and a theoretical signal for each of said subpopulations, acquiring a second signal from discrete sites from said first and second subpopulations and determining if said second signal from said discrete sites from said first and second subpopulations is within the threshold similarity measure determined for said first and second subpopulations, respectively.

Lockhart is described above.

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Walt also is described above.

The Examiner's position appears to be that Lockhart teaches each element of the claims except that they do not specifically teach a subpopulation of microspheres. However, the Examiner continues, microspheres were well known in the art as taught by Walt et al. The Examiner suggests that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the support of Lockhart with the bead-fiber substrate of Walt for the expected benefit of providing very high arrays of individually detectable beads as taught by Walt. Applicant respectfully traverses.

Initially, Applicant submits that the Examiner has failed to establish that the combination of the references teaches or suggests each element of claim 11. Specifically, as noted above in the response to the rejection of claim 12, Lockhart fails to teach or suggest a method that includes acquiring a reference signal by detecting a first signal in first and second channels.

In addition, Applicant notes that the Examiner has failed to point to any teaching in Walt that would cure the deficiencies of Lockhart. As such, Applicant submits that the references, either alone or in combination do not teach each element of claim 11.

As such, Applicant submits that a *prima facie* case of obviousness has not been established. Applicant respectfully requests the Examiner to withdraw the rejection.

#### Double Patenting

Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49, 53 and 54 of copending Application No. 09/636,387 in view of Walt et al. (6,327,410). Applicant

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maintains that they will consider filing a terminal disclaimer in the event there is an indication of otherwise allowable subject matter.

### CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the Office Action and, as such, the present application is in condition for allowance. Prompt and favorable consideration of this Amendment and Response is respectfully requested.

Please direct further questions in connection with this Application to the undersigned at (415) 781-1989.

Respectfully submitted,

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